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Review on Quality Aspects of Herbal Drugs and its Formulations

D. A. Patil, Sanjay K Bais, Jivan Tammaraya Biradar
Fabtech College of Pharmacy, Sangola, Solapur, Maharashtra, India

Abstract: *To evaluate the quality of pharmaceuticals, it is crucial to consider the quality factors of herbal remedies herbal formulations. The total of all elements that directly or indirectly affect the product's security, efficacy, and acceptance constitutes the quality of herbal medicines. The absence of formulation criteria, however, is a problem for herbal medications. The primary constraints are the absence of formulation for raw materials, processing techniques, and final goods, dose formulation, and the absence of quality control standards. To assure the quality, safety, and efficacy in herbal medicines using current, appropriate GMP standards.*

Keywords: Quality Control, Herbal Drugs, Medicinal Plants & GMP GLP Standardization

I. INTRODUCTION

1.1 General Introduction to Quality Aspects of Herbals

- **Herbal Drug:** Definition: flavoring medicines area unit those with active ingredients made up of plant components, like leaves, roots or flowers.
- **Raw Substance:** The flavouring materials are the raw elements. Plant parts such as roots, rhizomes, bark, seeds, fruits, leaves, flowers, and stems are sources of flavour ingredients. how much the raw ingredients are worthis supposed to refer to the amount of the flavouring preparations' active components.
- **Herbal Preparations:** A dosing form that contains 1 or more herbs, processed herbs, or both is referred to as a herbal formulation merely supplying certain organic processes, aesthetic edges intended for use in identifying and treating, reduce the severity of human or animal diseases, or change the anatomy or physiology of humans or animals

1.2 Quality in Terms of Herbal Drugs

1. The standing of a medicine is defined as its identity, purity, content, and other chemical, physical, or biological features, as well as the manufacturing techniques.
2. Genesis, Quality, safety, effectiveness, and consistency (QSEC) should be supported when using herbal remedies, phytotherapeuticals, and nutritional supplements.
3. Prior to the invention of salicylate in 1899, ancient medicine served as the only type of drug-based therapeutic method in a number of regions of the world.
4. Approximately 50,000 biologically active plants are identified worldwide over time. The world Health Organization has acknowledged this desire for a degree-based evidence base for all elements of old for numerous years (2002-2005, 2012), publications have made it obvious that the adoption of the introduction of traditional medicine (TM) into the nervous system needs to be supported by QSEC. The nutritional supplements and flavouring food-based pharmaceutical products have emerged as popular trends.
5. Intensifying police inquiry and surveillance.

1.3 Wild-Collected versus Cultured Materials

The quality of botanicals and flavours used in medicinal products is related to the livelihoods of different pricing chains and properties.3 Numerous rural areas and indigenous groups have been shown to, many people, especially in Asia, make their livings by collecting medicinal plants. The negative the deficiency within this wild assortment is due to the collected plants' depletion in the wild.

Together with their value, the market will expand. The only integrated chain with a degree

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Utilizing grown material could provide a better alternative to those models, however the most The finished product's significant increase in value at the distributor level is a significant drawback. Because the severity of the ongoing rise in air and soil pollution, particularly in Asian countries, pesticides,

1.4 Standardization

Standardization of procedures must encompass the entire field of study, from the cultivation of medicinal plants through clinical application, in order to reduce variation in final botanic products. internal management
The procurement of ingredients should be the first stage in the process of standardising the flavour of medications.
high quality content and the creation of standards for precisely identifying the components of every product, along with information on the function of the component combos. In the end, it's to prove its efficacy through biological tests and detect any negative effects impact profile from literature or from subsequent short- and long-term materia medica studies through a controlled clinical trial".

1.5 Constraints in Quality Determination of Flavoring Medicine

Limitations on how to evaluate the quality of flavoured medicine.
The activity for more than four hundredths of a plant extract is one of the most significant barriers to the use of plants in pharmacological development. The main disadvantage is dependability, as the once plants are re-sampled and re-extracted, activities recorded in screens typically don't reoccur. The usually, synergistic or additive effects are what give plant extracts and medicines their activity and effectiveness.
Impacts of the components' interactions. Consequently, a method should be adopted to determine the
Variations in the amount of material's bioactive phytochemicals on a qualitative and quantitative level.
The different agroclimatic or stress sites, climate, microenvironment, physical, andChemical stimuli that quantitatively and qualitatively change the quantity of secondary metabolites are commonly referred to as elicitorsElicitation-induced duplicable will therefore

1.6 Quality Analysis of Herbal Formulations

Raw Material Quality Evaluation

Morphological Evaluation

Herbal drug evaluation by size, form color, odor, style and specific characteristics like bit, texture etc. this is often a method of qualitative analysis associated with the study of morphological and sensory report of whole medication.

Microscopical Evaluation

It entails a thorough analysis of the drug, and it is customary to identify the organised drug by its renowned microscopic anatomy features. mostly employed for qualitative analysis with the aid of microscopic, of arranged crude drug in complete and powerful forms. Victimisation using a microscope, examine different biological layers, rhizomes, microscopic pores, starch granules, and metallic salt
A variety of crucial characteristics, including crystals and protein grains, are essential in the identification ofbinders for crude medicine.
All woody tissues provide pink colour, while starch and hemicelluloses are noted for their blue hue with iodine resolution. Strain using HCl and phloroglucinol, etc. Mucilage is coloured pink by Ru red, which is used to identify it.

Physical Analysis

Physical constants area unit typically taken into thought to judge bound medication. These embrace wet content, relative density, optical rotation, refractive, temperature, viscousness and solubility in several solvents. of these physical properties area unit helpful in identification and sleuthing of constituents gift in plants.

Chemical Analysis

The majority of medicines have defined chemical components that are responsible for either biological or pharmacologic effect. Qualitative chemical tests are rarely used to identify bound drugs or to verify their purity.

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Chemical methods of purification, identification, and isolation of active ingredients are used. Analysis resins analysis check: definite amount, sulphated ashBalsam analysis check: precise quantity, response value, bester values.
Values for acyl and organic component analysis of volatile oils.
The quantifiable chemical tests are useful for identifying and detecting chemical components of tampering.

Biological Analysis Methodology

Some drugs have particular biological and pharmacologic properties that are employed in their study. This activity is undoubtedly made possible by a certain type of ingredient present in the plant preparation.
In order to conduct the research, living animals' intact and isolated organs were used. With
With the aid of bioassays, the potency of the medicine during manufacture is assessed.
Quality control and method quality analysis
The raw ingredients used to make medicines are genuine, of the required quality, and free due to contamination
The manufacturing process follows the guidelines and upholds standards for purity. Adequate quality control methods are implemented, and the factory-produced medicine that is freely obtainable is of a respectable calibre to fulfil the higher-level goals set for each licensee shall

In method quality analysis and Quality assurance

Raw materials employed in producing of medicine area unit authentic, of prescribed quality and free from contamination. The producing method is as has been prescribed and maintains standards of purity. Adequate quality management measures area unit taken and The factory-made drug that is free purchasable is of acceptable quality. To reach the objectives listed higher than every licencee shall evolve methodology and procedures for manufacture of medicine that ought to be documented as a manual and unbroken for reference and review.[2]

Plant Premises

The industrial facility needs enough room for:
1. Receiving and storage raw materials;
2. Industrial zones
3. Internal control module and testing resources available on site.
4. The Finish Goods Shop Office
5. Bought a bad store

General Requirements

Far from open decomposing pollution, drains, and factories that produce offensive odours, gases, filth, or smoke.

Buildings

Clean and devoid of insects, rodents, and cobwebs made to prevent cross-contamination

A Water Source

Pure and suitable water quality. adequate laundry facilities on site.

Getting Rid of Waste

Follow predisposal treatment recommendations and pollution management advice.

Staff hygiene, clothing, sanitation, and health

An infectious disease-free environment for employees

Uniform

Suitable for the temperature and type of work, including appropriate head, foot, and hand protection.
covers for the head, feet, and hands.

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Facilities for Personal Hygiene

Clean towels, detergent, cleaning brushes, restrooms, change rooms, and a place to store personal items belongings. changing areas and a private area.

Services for Health

Initial care
Fresh herbs, dried herbs, or plant parts are raw ingredients derived from the animal food supply.
Ingredient, etc.
Volatile oils and fragrances
Plant exudates and extracts
Container is a must.
Lot/Batch No
Drug's Brand Name
Time of procurement

Determined By:

Procedure first Separate area for Unwanted raw materials in initial out
Separate area for raw materials that were rejected
Registered Stock.
packaging supplies
Bottles, jars, pills, etc. have their own housing.
Before packing the product, boxes and closure lids need to be properly cleaned and dried.
Cleaning
Testing
Storage restrictions on printed documents to prevent incorrect labelling employed house
Sufficient for the logical arrangement of goods and equipment.
To promote easy and secure operation
To reduce/eliminate the chance of confusion and cross-contamination

Equipments1.

1. Nature, diversity, and dimensions.
2. Installation and upkeep history.
3. Maintaining SOPs and all mill, sieves/ shifterChurna:Grinder/ disintegrator/ pulverizer, powdermixer, sieves.
Ark:Maceration tank, distillation plant, liquid filling tank with filter/ filter press, visual review box.
4.Operation. \se.ganjana Kharel/ball mill, sieves/shifter, pisti Churna: A grinder, a pulverizer, a mixer for powder, and sieves.

Batch manufacturing Record

Batch production Records
Records of the production of each batch of medicines
The following is a list of the items utilised and how much was purchased from the store.
Tests performed during the various manufacturing steps.

Finished Good Store

Stock space of Storage containing correct shelves & racks Proper packing and Labeling of finished product.
Approved Finished merchandise by internal control Labs.
Specific storage conditions

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GLP

GLP considers the framework and circumstances in which laboratory studies are planned, executed, monitored, documented, and rumoured.

Personnel:

To be led by a freelance associate. Duties:
To create testing procedures and specifications for raw resources and completed goods. sample, test, or
RMs, PMs, semi-finished products, and finished products can all be approved or rejected. to oversee and keep an eye on
The suitability of storage circumstances. keeping track of every procedure where testing is conducted
It is impossible to produce a finished good.

Records: Distribution Records and Processing And manufacturing Records (BMR) (to facilitate recall)
evidence of shelf-life and market complaints regarding negative drug reactions. [3]

Quality Control Legal Aspects & Documentation

Legal considerations and documentation quality control

1. The quality attributes of herbal products meet the requirements for an Ayurvedic herbal product. Identifying information and certification of the materials Ayurvedic-herbal product chemo- and bio-profiling. Protocols for verifying material purity, locating adulterants, replacements, and pathogenic microorganisms fungus, heavy metals, and chemical leftovers. the use of science to support statements made in antiquity research and clinical tests.

2. Quality Control: Applied mathematics quality management, production process control charts, sample schedules, automated method checks, indefinite quantity type checks, and testing4. Pharmaceutical Process Validation: programming techniques. systems for identifying products, adulteration, and misbranding. keeping of records. Bioavailability bio-equivalence. Dependability of the manufacturer data on the manufacturer and the medicine. pharmaceutical processing, packaging, and storage. control over components, containers, and closures. regulations on packaging and labelling. review for GMP compliance standard for potable water.

3. Style, construction, upkeep, equipment, and storage of the premises.

4. Validation of pharmaceutical processes: restricted basis, confirmation of sterile and non-sterile products product and consequent processes. Validation of the analytical method. the verification of computer-assisted processes.

Aspects of Drug Regulation: International and national drug regulatory organisations. Recent modifications to the federal food, drug, and cosmetic statutes. Applications for new drugs, studies on their effectiveness, reviews of their implementation and over-the-counter products, and drug listings. Recalls of drugs, product responsibility, the ICH points, clinical trials. ISO certification and a United Nations organisation. Trade, copyright, and patents marks.

6. Documentation: the relationship and significance of documentation, legal requirements, and protocol essential document assessment for documentation

They have a comfortable level of work competence and are educated and trained. The social, cultural, and economic
Any nation's progress is heavily reliant on its intelligent populace.

6. Documentation: connexion and importance of documentation, statuary necessities and procedure for documentation, vital examination of documents.

They are educated, trained, and have comfortable work expertise. The economic, social, and cultural developments of any country ar largely dependent upon its adept individuals.

This study aims at the role of adept human resources management and quality assurance system to achieving the competitive advantage for the organization.Human resource management ar the foremost vital part among the organization's parts, because, even a company owns all different resources (materials, financial, technological) while not the suitable, adept and older human resources, failure are the expected result.

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1. Testing in a Compliant and Timely Manner
The laboratory has adequate accommodation, facilities, trained personal and approved procedures to perform the testing in a very compliant and timely manner.

2. Approved Procedures
Sampling of raw materials, active pharmaceutical ingredients, intermediates, finished product and packaging materials are performed in keeping with approved procedures by trained personal.

3. Quality Assurance Program
The laboratory maintains a top quality assurance program, that's managed by employees that ar freed from undue influence that will have an effect on their judgement and therefore the correct discharge of their duties. The person responsible of the standard assurance program shall have direct access to the very best levels of management at that laboratory policy and resourcing selections ar created.

4. Education, Coaching and skill
All employees ought to be demonstrable competent, and qualified by an appropriate combination of education, coaching and skill to perform their allotted roles; and even be freed from any undue management, financial, industrial or different pressures that will compromise the integrity of their judgement and therefore the correct discharge of their duties.

5. Pre-Approved Testing plan
All testing is performed in keeping with a pre-approved testing arrange.

6. Validated
All analytical testing strategies ar fitly valid.

7. Documented
All analytical testing is documented and incontestable that testing was truly applied in keeping with written approved procedures.

8. Maintained and Calibrated
All instruments used for testing are appropriate for his or her purpose, perform to applicable performance specifications, ar maintained and graduated at regular intervals in keeping with a written schedule. Any instrument not playing to established specifications shall not be used.

9. Documented
Any deviations are fully documented and investigated

10. Established Specifications
Any deviations are absolutely documented and investigated.
All finished pharmaceutical product adapt to established specifications of identity, potency, purity and performance which {they ar|they're} packaged within the applicable containers and are properly labeled .

11. Results of inspections
The results of review and testing of raw materials, APIs, intermediates, bulk and finished product ar reviewed and assessed against established specifications, and such review and assessment is documented.

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12. Product Assessment

Product assessment includes reviewing ANd evaluating of product production records and an assessment of any deviations from established procedures.

13. before Certification

No batch of product is discharged for distribution before certification that's conforms to established specifications.

14. Retention Samples

Adequate retention samples of raw materials, active pharmaceutical ingredients, intermediates, and finished product ar maintained to allow future review and testing ought to this be needed, which finished product ought to be unbroken in their final packaging.[4]

Quality analysis of Finished product

The substances that occur naturally in plants are known as phytochemicals. These phytochemicals have gained a lot of popularity in recent years because to their countless health benefits. Phytochemicals are effective in fighting a variety of illnesses, including cancer, arthritis, and respiratory disorders.

The victimisation of phytochemicals' quality and quantity will be carried out. Chromatography of gases

The mass spectrometer (GCMS). GCMS will be used for samples that are solid, liquid, and foamy. First the samples are reborn into a frothy condition before analysis is conducted using the mass to charge concept.

Scale relationship Superior Performance Compounds that are soluble in solvents are said to have liquid activity.

For separation and detection, high - performing thin layer activity is appropriate. superiority and percentage of phytochemicals

Gas Chromatography

Volatile substances are suitable for gas natural action. Species are distributed among a gas as well as a liquid portion during this process. The liquid component is stationary because the gas component is in motion. once The sample particles are stationary in the liquid portion. Migration pace is determined by what A variety of chemical species are dispersed throughout the liquid portion.

Greater the percentage of fabric in the foam The migrations are faster. the organism that completely disperses itself within the stationary condition will not move. A sample will migrate at an interim rate if it evenly distributes itself across each phase. This Vapour is produced in complete by gas natural action. Consequently, it is typically utilised for chemical analysis.

High Performance Liquid Chromatography: (HPLC)

Another name for HPLC is High-Pressure Liquid Natural Action. This separates chemicals based on the idea that the solvent interacts with the solid particles in a tightly packed column.

The moving portion. The analyte must be washed under a high pressure of up to 400 bars.

Before they are detected, they pass through the column. When it comes to substances that can't be

That evaporate or break down at high temperatures. Each quantitative and qualitative chemical analysis performed all at once.

High Performance skinny Layer Chromatography: (HPTLC)

Chromatography with high performance thin layers: (HPTLC)

A modified variant of thin layer natural action can be called high performance thin layer natural action.

Wherever separation of high performance thin layer spontaneous action is used as a power tool

Sample components are finalised on high - performing layers using an acquisition and detection technique.

High-tech work station. The pre-coated substance on these high-performance layers is

5-7 microns in dimension and 150–200 microns in layer thickness

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Application of Chromatography for the quality evaluation of herbal drug and its formulation

[9:54 am, 20/01/2023] Rohit: Chromatography is used to evaluate the quality of herbal drugs and their formulations, as well as the presence of phenol in ayurvedic preparations. On colloidal sixty F 254 plates, natural activity was carried out with the mobile portion being 9 + 1 + 0.5 (v/v) toluene-ethyl acetate-methanol. Plates were created using a eight centimetres at temperature, but without chamber saturation. The licence plates were scanned, consequently, the substances were measured at the 420, 333, and 276 nm wavelengths where they absorbed light the most nm for each of the following: curcumin, piperine, and thymol. The unique R F ratios of piperine, curcumin, and phenol were 0, 0, and 0, respectively. the number was applied to the response, which was a linear operation.

Plate between 10 and 60 ng, 50 and 250 metric weight units, and 100 and 700 metric weight units for piperine, curcumin,

[9:57 am, 20/01/2023] Rohit: The ayurvedic formulation's turmeric, piperine, and phenol mean test findings were zero.85, 12.93, and 2.8 mg g-1, respectively. With curcumin, piperine, and phenol, respectively, the individual variances were 0.78, 0.51, and 0.69%. healing was fast detection of curcumin, piperin, and phenol, respectively, at 100.41, 99.52, and 101.21%

HPTLC Analysis using curcumin, piperine, and is a simple, accurate, quick, and cost-effective method.

It has been proven that effective excellent thin-layer natural process (Performance liquid chromatography (hplc) technology is suitable for

It is also possible to estimate curcumin, piperine, and phenol concurrently by spraying the plate.

with acid chemical age and anisaldehyde.[6]

II. CASE STUDY OF CURCUMA

It's possible that the East Indies are where turmeric is fully grown. Turmeric powder has a rich distinctive colour and a bitter flavour; it is used as a dye, ingredient in food, a chemical test's litmus test, and for beneficial purposes.

The Campus of Mississippi was granted a US patent for turmeric.

Medical centre established May 1995, primarily for the use of turmeric in the treatment of wounds.

Two years later, the Ministry of National research in India filed a complaint.

Research (CSIR) (CSIR).

According to CSIR, turmeric has been used medicinally in Asian nations for thousands of years.

As a result, the copyright on its medicinal usage wasn't entirely original.

Invention.

There is documentation evidence of cognitive content to back up the CSIR assertion ancient Sanskrit scripture, as well as.[7]

Quality evaluation methods of Herbal crude drugs and formulations 80 hrs

Select Minimum 2 to 3 crude drugs and carry out the following parameters

Determination of wetness content of crude medicine

Crude medicine area unit plants or animals that contain mutual substances that undergoes solely the method of assortment and drying moisture content determination is vital not solely to grasp the surplus water however conjunction with appropriate temperature. wetness can ends up in activation of enzymes and provides appropriate conditions to the proliferation of living organisms. various ways for wetness determination area unit loss on drying separation and mensuration of wetness chemical ways chemical analysis methodology as per IP

Procedure

1.10 metric weight unit of powder was weighed and placed in it a wetness content equipment

2. Temperature was adjusted to 100-110°c until weighed get constant and picked up in desiccator & weighed

3. The loss of weight was thought to be a live of wetness content as per IP.

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Fig: Moisture content of crude medicine

Determination of extractive price of crude medicine

Calculating the extraction price of crude medication The extractive price is an important factor to consider while analysing crude medicine. The less-extraction-intensive price denotes the inclusion of used-up materials, adulteration, or an improper procedure during formulation, drying, or storage. There are two forms of extractive price: alcohol and water-soluble.

Depending on the solvent employed. When using water as a solvent, it is referred to as

Extractive soluble price moreover, if alcohol is used in place of water, it is known as extractive price that dissolves in alcohol.

Determination of Extractive values

For the testing of a crude medication, these are useful. provides inspiration for the nature of the chemical components found in crude medication. beneficial for estimating components extracted using the extraction solvent. used for materials for which there has not yet been a suitable chemistry or biological test is available.

Preparations of the extracts

1. Prepare a cold maceration by macerating 5g of the good raw drug with 100 mil of liquid in an extremely tight flask. Over twenty-four hours, frequently shaking during the first six hours and allowing it to square lasted for 18 hours.
2. Filter quickly, taking care not to lose any solvent, and evaporating 25 ml of the filtrate until it is completely waterless.

To prevent the breakdown of organic phytochemicals, dry at one in an evaporating dish. 105 degrees Celsius, and weigh

3. Determine the ratio of soluble crude oil ether in water, alcohol, chloroform, and other solvents referring to the dry medication..[8]

III. CONCLUSION

1. Quality aspects that refers to processes involved in maintaining the quality or validity of drugs

2. To explore the many aspects of the rich herbal Drugs and herbal medicines

3. The popularity of herbal drugs has risen worldwide. This increase in usage renders safety issues important.

4. Quality issues of herbal drugs can be classified into two categories: external and internal. In this review, external issues including contamination (e.g. toxic metals, pesticides residues and microbes), adulteration and misidentification are detailed

5. Herb drug formulation shall mean a dosage form consisting of one or more herbs or processed herb(s) in specified quantities to provide specific nutritional, cosmetic benefits, and other benefits meant for use to diagnose treat, mitigate diseases of human beings or animals or to alter the structure or physiology of human beings or animals..

6. The .Formulation including some advantages are permanent cure cheap, eco friendly, safe, No adverse effects.

7. Theses formulations are done by physical chemical and biological evaluation method

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